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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,800	11/06/2000	Thomas Strungmann	4271-29PUS	5697

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/674,800	STRUNGMANN, THOMAS	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment filed 07/22/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. It appears that applicant's specification does not provide support for the limitation "mixtures thereof" in claims 32, 33, 36, 38, 39, 41, 43, 47, 49, 50 and 52. Further clarification is suggested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is rejected in the use of the limitation "polyurethane, polyisobutylene, polyvinyl ether, silicone, acrylate and mixtures thereof". The language is unclear,

because it is not consistent with the disclosure in the specification. Applicant's specification at page 7, lines 1-3 discloses "polyurethane-based, polyisobutylene-based, polyvinyl ether-based, silicone-based, and acrylate-based". Further clarification is suggested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 32-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frangin et al. US 5,985,915, in view of Poss US 5,616,591 and Jalonen et al. 5,464,628.

Frangin teaches a patch for transdermal composition comprising active ingredients, excipient (column 6, lines 24-65), and at least one additional cardioactive agent selected from the group consisting of diuretic, and angiotensin II, e.g., candesartan (column 8, lines 43-67, claims 14 and 35).

Regarding to claims 33 and 38 the reference differs from the claimed invention by not teaching the specific form of candesartan or its' salts. However, it would have been prima facie obvious for one of the ordinary skill in this art to, by routine experimentation determine a suitable form of candesartan suitable for transdermal patch.

The examiner notes that Frangin is silent as to the teaching of diuretic or calcium blocker as a second therapeutic agent. However, Frangin teaches the active ingredients selected from benzofuran can be formulated in combination with one or more pharmaceutically vehicles (see abstract). Thus, it would have been obvious for one of the ordinary skill in this art to select more than one cardioactive agent, e.g. diuretic and angiotensin inhibitor, to obtain a transdermal patch containing candesartan.

Frangin does not teach the claimed transdermal patch.

Poss teaches a composition for transdermal patch comprising an angiotensin inhibitor agent in combination with a diuretic agent as a second compound (columns 7, lines 40 through column 8, lines 1-29).

Poss and Frangin are relied upon for the reasons stated above. The references are silent as to the teaching of the ingredients of a transdermal patch.

Jalonen teaches a pharmaceutical composition containing substituted imidazole to be administered transdermally (abstract). The transdermal patch comprises an impermeable backing layer and an adhesive layer; or an impermeable backing layer, an adhesive layer, and a matrix layer; or a drug reservoir system (column 2, lines 36-64). The backing layer can be flexible or non-flexible materials: polyethylene, or polypropylene; the adhesive layer can be polysiloxanes, polyisobutylene, polyacrylates, ethylene-vinyl acetate, acrylate, polyurethane, and silicone; and the matrix layer can be of natural or synthetic rubbers (column 3, lines 21-51). The composition further comprising carrier and penetration enhancers, e.g., polyethylene glycol, propylene glycol, isopropanol, ethanol, oil, or a mixture thereof (column 2, lines 65 through column

3, lines 1-20). Thus, it would have been obvious for one of the ordinary skill in this art to prepare the composition of Poss and Frangin in a transdermal patch in view of the teaching of Jalonen. The reason for this modification is to obtain a candesartan transdermal patch that will provide a high bioavailability of drug penetration.

Response to Arguments

Applicant's arguments filed 07/22/04 have been fully considered but they are not persuasive.

Applicant argues that Frangin does not provide enabling disclosure to teach administration of even the principal active agent (benzofuran derivative) via a transdermal "patch" delivery system in that it does not provide enabling disclosure as to the type and construction of such a patch that could be utilized for the delivery of the benzofuran derivative. In response to applicant's argument, first, Frangin does teach that his composition can be formulated as a transdermal patch (column 6, line 36). The active ingredients to be incorporated into his composition includes candesartan (column 8, line 67). Second, Frangin is cited in combination with Poss and Jalonen.

Applicant argues that Poss does not disclose or even mention candesartan, which although an angiotensin II inhibitor, is not, in any case, one of the class of indole and benzimidazole-substituted quinoline derivative compounds. Poss is cited solely for the teaching of angiotensin II inhibitor can be administered transdermally. Frangin at column 8, lines 66-67 has defined angiotensin II inhibitor includes candesartan.

Applicant argues that not all therapeutically active substances are suitable for transdermal administration (cited Jalonen, column 2, lines 13-29), and therefore, any broad conclusion of obviousness is not warranted and the art specifically teaches away from such a broad conclusion. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. Jalonen is cited solely for the teaching of transdermal patch. Jalonen teaches a transdermal patch comprising active drugs, including, antihypertensive active agent for the treatment of hypertension (column 1, lines 41-50). Candesartan is a well known for the treatment of heart disease, and hypertension. Therefore, it is the position of the examiner that it would have been obvious for one of ordinary skill in the art to modify the compositions of Frangin and Poss using the transdermal patch taught by Jalonen, because Frangin teaches the use of transdermal patch to deliver angiotensin II inhibitor, because Poss teaches transdermal is a prefer route of administration of an angiotensin II inhibitor, and because Jalonen teaches a transdermal patch comprising active drugs, including, antihypertensive active agent for the treatment of hypertension.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER
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